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AUG 1 3 2001

**SULZER***MEDICA*

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# Summary of Safety and Effectiveness

Prepared on April 17, 2001

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

**Trade Name:** IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis

**Manufacturer:** Sulzer IntraTherapeutics, 651 Campus Drive, St. Paul, MN 55112
Tel. 651-697-9797 Fax 651-697-4808

**Official Contact:** Amy Peterson, Vice President RA & QA
Tel. 651-697-2076

**Device Generic Name:** Biliary catheter

**Classification:** Class II product classified under 21 CFR §8768.5010 as a biliary catheter and accessories. Product Code: FGE.

**Predicate Devices:** IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis (K003997)

**Device Description:** The 316L stainless steel stent is premounted onto a nylon balloon delivery catheter designed to be used with an 0.035" guidewire.

**Indications for Use:** Palliative treatment for malignant neoplasms in the biliary tree.

**Safety & Performance:** The following *in vitro* functional tests were performed:

- Crossing profile
- Stent retention/bend radius
- Stent securement force
- Expansion force
- Deployment accuracy
- Dimensional testing
- Balloon inflate/deflate time
- Balloon fatique – 20 cycles
- Balloon burst strength
- Effects of balloon rupture on stent
- Stent recoil

New biocompatibility tests were not performed based on the equivalence of the intended use, materials and manufacturing methods. Previous testing was compliant with ISO 10993-1.

**Conclusion:** Based on the indication for use, technological characteristics and safety and performance testing, the modified IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2001

Ms. Amy Peterson
Vice President, Regulatory Affairs and Quality Assurance
Sulzer IntraTherapeutics, Inc.
651 Campus Drive
St. Paul, Minnesota 55112

Re: K011184
IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis
Dated: July 11, 2001
Received: July 12, 2001
Regulatory Class: II
21 CFR §876.5010/Procode: 78 FGE

Dear Ms. Peterson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device

in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011184

Device Name: IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis

FDA's Statement of the Indications For Use for device:

The IntraStent® DoubleStrut™ ParaMount™ XS Biliary Endoprosthesis is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011184